UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA and the COMMONWEALTH OF MASSACHUSETTS, Relators, ex rel. LISA WOLLMAN, M.D., Relator-Relator, v. THE GENERAL HOSPITAL CORPORATION (d/b/a the Massachusetts General Hospital), THE MASSACHUSETTS GENERAL HOSPITAL'S PHYSICIAN'S ORGANIZATION and PARTNERS HEALTHCARE SYSTEM, INC. Defendants.	Civil Action No. 15-11890-ADB

DEFENDANTS' MEMORANDUM OF LAW
IN SUPPORT OF MOTION TO DISMISS

Following notices filed by the Department of Justice and the Massachusetts Attorney General's Office stating their intention, after nearly two years of investigation, *not* to intervene in this qui tam case, Relator Lisa Wollman amended the complaint she had filed two years ago against The General Hospital Corporation, The Massachusetts General Hospital Physician's Organization, and Partner's Healthcare System, Inc. (collectively, "MGH"). Relator's amended complaint, ("Am. Compl."), Docket Entry 31, makes unspecified allegations that MGH violated the federal and state False Claims Acts by making claims for payment that violated Medicare and Medicaid rules describing when surgeons may properly bill for participating in surgeries.

Like her original complaint that the government chose *not* to pursue, and in an apparent attempt to disguise the lack of particularized allegations that her fraud claims require, Relator has filled her amended complaint with broad, generalized allegations regarding quality of care and medical ethics. Such allegations have no bearing on the *billing* claims asserted under the False Claims Acts, which are meant to address "allegations of fraud, not medical malpractice." *Universal Health Services, Inc. v. U.S. ex rel. Escobar,* 136 S. Ct. 1989, 2004 (2016). Moreover, Relator has not alleged—and truthfully could not allege—that *any* of the reviews of MGH's practices conducted by the appropriate accreditation and licensing agencies found patient safety or ethics concerns. MGH is a renowned academic medical center that prides itself on excellence in patient care and vigorously disputes any allegations that its surgical practices compromised patient care or violated medical ethical rules.

While MGH is confident that the evidence would demonstrate the specious nature of Relator's claims, the amended complaint should be dismissed now because it:

- fails to satisfy the requirements of Fed. R. Civ. P. 9(b), which requires that False Claims Act allegations be pled "with particularity";
- fails plausibly to allege that MGH violated any relevant billing rule, or that any purported violation was material; and
- fails plausibly to allege that MGH acted with the requisite scienter.[1]

Relator already has had two years to do the work necessary to state a claim (if, in fact, such a claim *could* properly be alleged—something MGH also disputes). MGH therefore asks the Court to dismiss Relator's complaint with prejudice.

BACKGROUND

I. Federal and State Rules Permit MGH to Bill for Overlapping Surgeries.

Relator's generalized "allegations of fraud" center on her claim that MGH violated a specific Medicare and Medicaid billing rule when MGH submitted claims for teaching physicians' participation in two or more surgeries scheduled to start, she alleges, at nearly the same time. Assessing this claim requires examination of the billing rule at issue to see not only what it requires but, more importantly, *what it does not require*.

Federal regulations, *see* 42 C.F.R. § 415, and the more detailed rules set forth by CMS in the Medicare Claims Processing Manual, ch. 12, § 100, permit teaching hospitals such as MGH to bill for a surgeon's participation in an operation even when the surgeon does not personally perform the surgery—even *any part* of the surgery. Medicare pays for surgeons' services furnished in teaching settings through the Medicare Physician Fee Schedule if the services are "personally furnished by a physician who is not a resident" *or*

[1] As Relator concedes, other doctors raised concerns about MGH's practices before she did, which resulted in reviews by state regulatory agencies. *See* Am. Comp. ¶ 109. Should the need arise, defendants reserve the right to assert other defenses based on questions raised by the amended complaint, including whether the False Claims Act's public disclosure bar precludes Relator from recovering, *see* 31 U.S.C. §3730(e)(4)(A); which, if any, of the named defendants may properly be defendants based on her allegations; and other defenses.

are "furnished by a resident *in the presence of a teaching physician*" so long as certain conditions are met. *See* 42 C.F.R. § 415.170 (a)-(b) (emphasis added).

The Medicare Claims Processing Manual, ch. 12, § 100.1.2(A)(2) (2017), provides explicit guidance. It sets out a rule—for convenience, this Memorandum calls it the "overlapping surgery billing rule"—that permits a teaching physician to bill for two overlapping surgeries so long as that surgeon complies with these basic conditions:

1. Presence during key and critical portions: "In order to bill Medicare for two overlapping surgeries, the teaching surgeon must be present during the critical or key portions of both operations. Therefore, the critical or key portions may not take place at the same time. When all of the key portions of the initial procedure have been completed, the teaching surgeon may begin to become involved in a second procedure."

2. Documentation: "The teaching surgeon must personally document in the medical record that he/she was physically present during the critical or key portion(s) of both procedures."

3. Arranging for qualified surgeon for non-key and non-critical portions: "When a teaching physician is not present during non-critical or non-key portions of the procedure and is participating in another surgical procedure, he/she must arrange for another qualified surgeon to immediately assist the resident in the other case should the need arise."[2]

See 42 C.F.R. § 415.172(a); Medicare Claims Processing Manual, ch. 12, § 100.1.2(A)(2) (2017). These are the only conditions that expressly apply to billing for overlapping surgeries in a teaching setting.[3]

The overlapping surgery billing rule thus gives teaching physicians broad discretion, relying on their expertise and experience, to decide how to operate. First, as noted, it allows a surgeon to bill Medicare for procedures even when the surgeon chooses to permit a resi-

[2] This part of the guidance aligns with § 415.172(a)(1): "In the case of surgical, high-risk, or other complex procedures, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure."

[3] MassHealth Medicaid provisions are nearly identical. *See* Am. Compl. at ¶¶ 52-56.

dent to perform the procedure, so long as the teaching physician is present during the key and critical portions of a surgery.

Second—and this point is crucial in evaluating Relator's claims—the billing rule does not define the "critical or key" portions of procedures (that is, the parts the teaching physician must be present for). Instead, it permits the teaching physician to determine the parts of a particular procedure he or she deems key or critical. *See* Medicare Claims Processing Manual, ch. 12, at § 100. CMS' decision to let the teaching surgeon decide what parts of a surgery are key or critical is "intended to recognize both the expertise of the individual surgeon in making such a determination and that the critical portions can vary based upon the expertise of the residents, fellows, or technicians assisting in the operation or by the condition of the patient." *See* Concurrent and Overlapping Surgeries: Additional Measures Warranted, Senate Finance Committee Staff Report, Dec. 6, 2016, p. 9, cited by Am. Compl. at ¶¶ 45, 101; *see also* ¶¶ 134, 135.

Third, the overlapping surgery billing rule does not define the term "immediately available." Likewise, it does not prescribe a particular method a teaching physician must use to "arrange for another qualified surgeon to assist the resident *should the need arise*" or describe *when* a teaching physician must make such a designation.

Moreover, nothing in the overlapping surgery billing rule prescribes patient safety guidance for academic medical centers, or regulates how teaching hospitals must run their operating rooms.[4]

[4] Even "*triple* booked" surgeries are not prohibited by the overlapping surgery billing rule—hospitals may simply not bill Medicare for those surgeries. While providers are prohibited from billing a teaching physician's time in overseeing them, the rationale is not patient safety but rather that the teaching physician is performing a "supervisory service to the hospital rather than physician service to an individual patient." *See* Medicare Claims Processing Manual, 100.1.2(A)(2).

II. Relator's Allegations.

Relator's central claim is that that that MGH routinely violated the overlapping surgery billing rule when MGH surgeons "booked two or three surgeries, each lasting three or more hours, for different patients . . . scheduled to start within 15-30 minutes of one another." Am. Compl. at ¶ 1. Relator allegedly became aware of these practices in 2010, when she was assigned to provide in-patient anesthesia services to surgical patients in MGH's Department of Orthopedic Surgery. *Id.* at ¶¶ 16-17. Despite the purportedly wholesale nature of MGH's violations of the overlapping surgery billing rule, Relator fails to point to even one particular instance of a false request for payment. Instead, she relies on the conclusory assertion that *all* of MGH's requests for Medicare or Medicaid payments (not a single one of which has been identified) *must* have been false because MGH routinely violated the specific procedural requirements of the overlapping surgery billing rule.

Specifically, Relator alleges that MGH violated the False Claims Act by failing adequately to inform patients that one of the physicians on the surgical team might be involved in overlapping surgeries; routinely administering more anesthesia than would have been administered had surgeries not overlapped; and failing to keep adequate surgical records. *See* Am. Compl. at ¶¶ 57-59, 86-92; Am. Compl. at ¶¶ 60-62, 93-105; Am. Compl. at ¶¶ 49-50, 56, 106-108. Each of these allegations falls well short of pleading a viable claim**.**

ARGUMENT

I. The Court Should Dismiss the Amended Complaint with Prejudice.

The Court should dismiss the amended complaint for three reasons. *First,* causes of action under the Federal Claims Act are subject to the heightened pleading standards for allegations of fraud, and Relator's allegations fall very far short of this high standard. *See*

Fed. R. Civ. P. 9(b). *Second,* Relator has failed adequately to plead that MGH in fact violated any Medicare billing rule, and certainly failed to claim plausibly that any supposed violation was "material," a necessary element of any False Claims Act case. *Third,* Relator has failed to allege scienter—i.e., that Defendants knowingly made or presented a false claim for payment.

There is no reason to believe that any of these shortcomings can be remedied through further amendment. The case law makes clear that Relator is not entitled to discovery to attempt to meet the heightened pleading standard, *see United States ex rel. Karvelas v. Melrose-Wakefield Hospital*, 360 F.3d 220, 231 (1st Cir. 2004). Therefore, her complaint should be dismissed with prejudice.

A. Relator Fails to Meet the Heightened Pleading Standard for Alleged Fraud.

1. *Claims under the False Claims Act Are Subject to Rule 9(b).*

Rule 9(b) provides, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." In order to make out a claim under the federal False Claims Act, a Relator must prove, at a minimum, (i) that the defendant submitted or caused the submission of a claim for payment to the government, and (ii) that the claim for payment itself was false or fraudulent. *Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26, 31 (1st Cir. 2016). Both elements must be pled with Rule 9(b) particularity, and courts routinely dismiss claims False Claims Act complaints where they are not sufficiently particularized. *Id.* at 29-31 (affirming dismissal with prejudice for failure to meet Rule 9(b) pleading standard); *see Karvelas*, 360 F.3d at 227 ("… we now join th[e] consensus and hold that Rule 9(b) applies to claims under the FCA.").

To comply with this standard, Relators must set forth with particularity the "who,

what, when, where, and how" of the alleged fraud. *United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 123 (1st Cir. 2013). This standard is purposefully high to prohibit Relators from relying on the discovery process to fill in the gaps in what they purportedly know about practices they believe are unlawful. *See Karvelas*, 660 F.3d at 231. As the First Circuit explained in *Karvelas*:

> [A] Relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a Relator state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in a complaint. However, … we believe that 'some of this information for at least some of the claims must be pleaded to satisfy Rule 9(b).'

Id. at 232-33; *see also United States ex rel. Williams v. City of Brockton*, 2016 U.S. Dist. LEXIS 178032, *23-24 (Dec. 21, 2016) (Talwani, J.).[5]

2. *Relator Fails to Allege Facts with the Required Particularity.*

Relator's allegations fall well short of the particularity required under Rule 9(b). Despite the fact that Relator worked at MGH for ten years, served as an anesthesiologist for orthopedic surgery from 2010 to 2015, and apparently began reviewing patient medical rec-

[5] While the First Circuit applies a more flexible standard where a Relator alleges that the defendant caused a third party to submit a false claim to the government, that standard does not apply where, as here, Relator alleges that defendants themselves submitted allegedly false claims. *See United States ex rel. Kelly v. Novartis Pharms. Corp.*, 827 F.3d 5, 13 (1st Cir. 2016) (noting that, in cases of third-party inducement, a relator satisfies Rule 9(b) providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim"). Even if the relaxed standard applied, Relator has failed to satisfy it because, as detailed *infra*, at most she has pled that fraud was possible. *See id.* ("[I]t is not enough simply to 'rais[e] facts that suggest fraud was possible….").

ords for evidence of concurrent and overlapping surgery as early as 2011, Am. Comp. at ¶¶ 3, 11, 69, the amended complaint does not contain a single allegation describing a particular claim for payment—i.e., no details concerning: (i) the dates of the claims, (ii) the content of the forms or bills submitted, (iii) their identification numbers, (iv) the amount of money charged to the government, (v) the particular goods or services for which the government was billed, (vi) the individuals involved in the billing, (vii) or the length of time between the alleged fraudulent practices and the submission of claims based on those practices. *See Karvelas*, 360 F.3d at 232-33.

Unable to allege any facts with the required particularity, Relator instead resorts to generalized and conclusory allegations based on guesswork. *See, e.g.*, Am. Compl. at ¶ 92 ("[V]irtually, every claim by Defendants for concurrent surgeries contains inflated charges for anesthesia services and is a false claim."); *Id.* at ¶ 105 ("Defendants submitted false claims to the government for all Medicare/Medicaid patients receiving surgery in tandem or concurrently with one or more other patients because the hospital did not obtain valid informed consent for these patients."); *Id.* at ¶ 108 ("Defendants submitted false claims to the government for all concurrent surgeries where the surgeon's records do not comply with regulations."). Conclusory allegations of this nature are insufficient to establish a viable claim and not a license to go on a fishing expedition for evidence of fraud. *See Karvelas*, 360 F.3d at 231-33; *see also United States ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240 (D. Mass. 2015), *aff'd*, 844 F.3d 26 (2016) ("Rule 9(b), however, requires something more than conclusory allegations that false claims must have resulted from the misconduct.").

At most, Relator cites some outdated statistics and makes assumptions based on the

alleged age of patients to show that it is *possible* defendants submitted false claims. *See, e.g.*, Am. Compl. at ¶ 8, n.7 (alleging that, nationally, Medicare was primary payer for 63.3% of knee replacements and 58.2% of hip replacements in 2000, and 54.7% of knee replacements and 52.8% of hip replacements in 2009); *Id*. at ¶¶ 69, 70, 75 (alleging that patients were over 65 and therefore "Medicare eligible."); *Id*. at ¶ 72 (alleging that patients were in their seventies and "most likely Medicare patients").

This approach fails to meet the exacting standard established by the First Circuit. *See Karvelas*, 360 F.3d at 228-31. Allegations regarding Medicare "eligibility" are insufficient. *See Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26, 32 (1st Cir. 2016) ("[W]ithout any allegation that the patients were actually covered by government programs or that certain replacement procedures conducted on these patients were medically unnecessary, [Relator] has 'at most … [only] raise[d] facts … suggest[ing] fraud was possible.'").[6]

Even if Relator could survive a Rule 9(b) motion based on allegations of Medicare eligibility, her complaint still fails because she has not matched up any particular Medicare-eligible procedure with any alleged violation of the overlapping surgery billing rule. Indeed, given the discretion accorded physicians in billing under that rule, doing so presents insurmountable challenges. As noted above, Medicare and MassHealth have explicitly given teaching physicians the role of deciding what portions of surgeries they perform are key or critical. To plead fraud with particularity, Relator would have to identify, at a minimum, specific surgical procedures in which a surgeon was not present for portions of the surgery that *that* surgeon deemed key or critical.

[6] *Hagerty* was decided under the more lenient standard applicable to FCA cases in which a Relator alleges that the defendant induced a third party to file a false claim. As noted in n.5 *supra*, this standard is not applicable in this case, but Relator's allegations would not satisfy even this more lenient standard.

3. *Plaintiff's Identification of Particular Surgeries Does Not Satisfy the Particularity Requirement.*

Plaintiff's descriptions of MGH surgical schedules, evidently offered to suggest that she had satisfied the requirement of particularity, only underscores her failure to comply with Rule 9(b). Plaintiff's five years in the orthopedic operating room—a time when she claims violation of billing rules was routine—resulted in allegations about supposed concurrent surgeries *scheduled* to be performed on some sixteen dates over four years—about four dates a year. *See* Am. Comp. at ¶ 65-74. Moreover, Relator's allegations about the procedures on those sixteen dates show that she cannot satisfy the particularity requirement.

- *First:* Relator never alleges that MGH actually submitted a claim to Medicare or MassHealth for *any* of the surgeries Relator identifies.
- *Second:* Relator never identifies a particular procedure where a teaching physician was not present for the components of that procedure the surgeon defined as key or critical or that MGH submitted a claim for any such procedure.
- *Third:* Relator never—again, not even once—identifies an occasion when two surgeries overlapped, and the key and critical portions of those two surgeries (as defined by the surgeon) occurred at the same time.

Her complaint therefore must be dismissed.

B. Relator Fails Adequately to Plead that Any Alleged Billing Rule Violation was Material.

1. *Materiality under* Escobar.

Not every violation of government billing regulations gives rise to a false claim. In order to be actionable under the False Claims Act, a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision. *See Universal Health Services, Inc. v. U.S. ex rel. Escobar,* 136 S. Ct. 1989 (2016) ("*Escobar*"). Between the Relator's filing of her initial and amended complaints, the Supreme Court clarified how courts should enforce the "materiality" require-

ment .[7] The Court held: "What matters . . . is whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Id.* at 1996.

The Court stated that the materiality standard is rigorous and demanding; materiality "cannot be found where noncompliance is minor or insubstantial." *Id.* at 2003. "The False Claims Act is not an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* (internal quotations and citation omitted). *Id.* A misrepresentation cannot be deemed material solely because a Relator failed to comply with a designated condition of payment or because the Government would have the option to decline to pay if it knew of the defendant's noncompliance. *Id.* The Court enunciated the factors to be considered:

> In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003-04. In so ruling, the Court explicitly rejected the then prevailing First Circuit

[7] The term "material" as used in 31 U.S.C. § 3729(a)(1)(B) is defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The Court held that it need not decide whether § 3729(a)(1)(A)'s materiality requirement is governed by §3729(b)(4) or derived directly from the common law because under any understanding of the concept, materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation. *Escobar*, 136 S. Ct. at 2002.

view that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation. *Id.* at 2004. The Court also rejected the contention that materiality is too fact intensive for courts to decide on a motion to dismiss, noting "False Claims Act Relators must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality." *Id.* at 2004 n.6.

2. *Relator Fails to Allege that Any Violation of the Overlapping Surgery Billing Rule Was Material.*

Although Relator added a new section devoted to materiality to her amended complaint (*see* ¶¶ 131-36), her allegations fall well short of the standard established by the Supreme Court in *Escobar*. Relator alleges that "[t]he expectation that critical surgeries are performed by fully credentialed and qualified physicians and that patients are fully informed as to all material elements of their surgeries is at the very core of the regulatory scheme. Violation of these requirements is material…" Am. Compl. at ¶ 131. Contrary to Relator's assertion, the overlapping surgery billing rule does not require that the teaching physician "perform" the surgery. It requires only that the physician be present during the critical or key portions of both operations.

Relator alleges that the centrality of these regulations is underscored by their inclusion as a condition of participation and prerequisite for reimbursement, and by the "extensive interpretive guidelines issued by CMS." *Id*. at ¶ 132. She also states that "CMS emphasized the materiality of appropriate record-keeping by providing detailed guidance on documentation." *Id.* at ¶ 133. Relator's allegations are not sufficient, certainly not under the "rigorous and demanding" materiality standard announced in *Escobar*. Under *Escobar,* the

question is whether the Relator has plausibly alleged that MGH's alleged failure to comply with this so-called detailed guidance would have caused the government to reject MGH's claim for payment. Extensive or detailed "guidance" from CMS is not the touchstone of materiality; CMS offers extensive guidance on a myriad of issues related to billing.[8] While inclusion of a provision as a condition of participation is relevant, it is "not automatically dispositive." *Escobar*, 136 S. Ct. at 2003.

Relator also alleges that the materiality of Defendants' alleged Medicare and Medicaid violations is underscored by "the Government's consistent action to punish and deter the conduct at issue." Am. Compl. at ¶¶ 134-36. These allegations are contradicted by the very source Relator relies on throughout her complaint: the Senate Finance Committee Staff Report entitled Concurrent and Overlapping Surgeries: Additional Measures Warranted (Dec. 6, 2016) ("Senate Staff Report").

- The Senate Staff Report shows that, in fact, the government has taken little action to regulate this area: "*CMS* officials … told Committee staff that they have never undertaken a study to determine whether the surgical procedures Medicare paid for met CMS' billing requirements specific to overlapping surgeries performed in teaching hospitals." (*Id.* at 6);
- "Similarly, officials with AHRQ, the agency within HHS charged with researching how to improve *health* care quality and reduce medical errors, told Committee staff that the agency had not conducted any research related to concurrent or overlapping surgical practices." (*Id.*);
- "Officials with HHS OIG also told Committee staff that they do not have any ongoing work specifically reviewing hospitals' adherence to the Medicare billing requirements for teaching physicians." (*Id.* at 7).

[8] The Medicare Claims Processing Manual is over 4,500 pages. It includes detailed and expansive guidance on countless issues related to the submission of claims, including issues as mundane as the format of dates on billing forms. To conclude that a topic is material solely because the manual includes detailed guidance on it would do away with materiality altogether.

Although Relator alleges that "between 1995 and 2004, HHS OIG reported that 36 teaching hospitals settled False Claims Act or other similar cases related to audits of billing practices," *see* Am. Compl. at ¶¶ 134-35, there is no indication that any of these settlements related to overlapping surgeries. In fact, the Senate Staff Report clarifies that the University of Pennsylvania Medical Center case highlighted in Relator's complaint, *see* Am. Compl. at ¶ 135, was "not directly related to concurrent or overlapping surgeries." Senate Staffing Report at 7. Moreover, the Report notes that "[n]otwithstanding CMS billing restrictions in this area, neither CMS's COPs [Conditions of Payment] nor CMS's interpretive guidelines, which describe the COPs and provide survey procedures used to determine compliance with them, mention the practice of concurrent or overlapping surgeries." *Id.* at 2. "CMS has not taken any steps to determine whether the existing billing requirements applicable to teaching physicians in hospitals are or are not being followed despite a history of problems in this area." *Id.* at 18. The fact that the government continues to pay claims for overlapping surgeries and has explicitly signaled that there is no change in its position, or plans to further investigate changing its position, is strong evidence that specific technical requirements of the overlapping surgery billing rule are not material for purposes of the False Claims Act. *See Escobar*, 136 S. Ct. at 2003-04. Relator has not sufficiently pled materiality, and her complaint must be dismissed.

C. Relator Fails to Allege MGH Violated Any Condition of Payment Related to Informed Consent, or that Any Such Violation Was Material.

Relators' amended complaint alleges that Medicare and Medicaid make informed consent a condition of participation in the Medicare and Medicaid programs. *See* Am. Compl. at ¶¶ 60-62. Relator does not allege, however, that either Medicare or Medicaid regulations prescribe a particular form of words that teaching hospitals must use to obtain con-

sent from patients whose surgeons may be conducting overlapping procedures. *See id.* In fact, Medicare requirements regarding consent forms are far more limited than Relator suggests. Hospitals providing surgical services are required to ensure that a "properly executed consent form for the operation must be in the patient's chart before the surgery," but the rules do not include any requirements regarding the precise content of such a form. *See* 42 C.F.R. 482.51(b)(2).

As Relator points out, CMS has promulgated interpretive guidelines, but the guidelines further undermine her position in two key respects. *First*, the guidelines state at the outset that "they contain discussion and examples of practices which hospitals are encouraged to adopt, but which are not necessarily required . . .." Guidelines, Memorandum Summary, at 2. *Second*, and more importantly, they make clear that the primary purpose of the informed consent process is to present the patient with information as to the "potential short- and longer-term risks and benefits to the patient of the proposed intervention, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's professional judgment." 2007 CMS Hospital Interpretive Guidelines for Informed Consent, at A-0392.[9] In other words, there is nothing in the Guidelines to suggest that MGH's consent form—which Relator admits has disclosed for at least sixteen years that residents, fellows, and students may be involved in a patient's procedure—is in violation of the Medicare billing requirements.[10] Nor can Relator claim that the MGH's decision not to use the form of words Relator now contends is appropriate constituted a mate-

[9] Available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter07-17.pdf

[10] The portion of the Guidelines excerpted in paragraph 62 of Plaintiff's complaint is merely an "example" of a well-designed informed consent process. 2007 CMS Hospital Interpretive Guidelines for Informed Consent, at A-0392. Moreover, the guidelines themselves are intended to be used as survey procedures.

rial violation of a billing rule. Where CMS chose not to prescribe a particular set of words, MGH would not "know" that its failure to adopt the consent form Relator would prefer was a violation of a "requirement that the defendant knows is material to the Government's payment decision." *Escobar*, 136 S. Ct. at 1996.[11]

D. Relator Fails to Allege that MGH Violated Any Anesthesia Billing Rule, or that Any Such Violation Was Material.

Relator contends, in essence, that MGH's overlapping surgery practices resulted in some patients being placed under anesthesia for longer periods than they would have been if MGH did not permit overlapping surgeries. *See* Am. Comp. at ¶¶ 57-59. Relator acknowledges that Medicare "reimburses anesthesia practitioners for the period of time during which they are 'present with the patient.'" Am. Compl. at ¶ 57. She alleges that MGH's practice of permitting surgeons to perform overlapping procedures resulted in patients receiving anesthesia for longer periods than medically necessary, as they waited for their surgeon to complete another procedure. This, Relator claims, violates the Medicare requirement that MGH bill only for those services that are "reasonable and necessary." *Id*. at 58.

Here, too, Relator fails to allege either a plausible violation of any billing rule, or facts establishing that any potential violation might be material. Relator points to no specific time limits set forth by CMS for patients to wait on anesthesia. And, as set forth herein, CMS explicitly permits surgeons to engage in overlapping surgeries. Accordingly, MGH could hardly be ex-

[11] Relator further contends that "codes of medical ethics have long warned that concurrent surgeries, in the manner conducted by defendants, are unethical." Am. Compl. at ¶ 133. Even if this were true, Relator's reliance on codes of medical ethics is misplaced. The billing rule at issue here expressly *allows* overlapping surgeries so long as the appropriate requirements are met—most notably, the requirement that the surgeon be present for key and critical parts of the surgery as s/he describes them.

pected to "know" that anesthesia delays allegedly incident to its decision to permit surgeons to perform overlapping procedures was a violation of a billing "requirement that [was] material to the Government's payment decision." *Escobar*, 136 S. Ct. at 1996.

E. Relator Fails to Allege that MGH Violated Any Record Keeping Rule, or that Any Such Violation was Material.

Relator also alleges that MGH violated the False Claims Act because MGH maintained inadequate records. Am. Compl. at ¶¶ 106-07. But there is a substantial disconnect between what the Medicare billing rules require and what Relator evidently wishes they required. The billing rule Relator cites states only that: "The medical records must document the teaching physician was present at the time the service is furnished. The presence of the teaching physician during procedures may be demonstrated by the notes in the medical records made by a physician, resident, or nurse." 42 CFR 415.172. This aligns closely with the overlapping surgery billing rule itself, which states that "[t]he teaching surgeon must personally document in the medical record that he/she was physically present during the critical or key portion(s) of both procedures." *See* 42 C.F.R. §415.172(a).

What plaintiff claims MGH should have documented is altogether different. Relator claims that MGH "routinely failed to provide an accurate accounting of the teaching surgeon's involvement in the case, including the nature of the procedures deemed to be 'key and critical,' the time in which he entered and exited the surgery room, whether he was able to return to the surgery if necessary, and /or whether another surgery was conducted at the same time." Am. Compl. at ¶ 106. She also alleges that MGH's records did not contain "the name of a back-up teaching physician who was in fact available and qualified to take over if necessary." *Id*. at ¶ 107. Once again, plaintiff seeks to hold defendants to standards that simply do not exist in the applicable regulations. And on the question of a material viola-

tion, again, if the government did not require hospitals to maintain the kind of records Relator wishes were required, how could MGH could not possibly "know" that its alleged failure to keep the kind of records Relator thinks appropriate was "material to the Government's payment decision." *Escobar*, 136 S. Ct. at 1996.

F. Relator Fails to Adequately Plead Scienter.

The amended complaint should be dismissed for an additional reason: Relator has failed to plead scienter—that is, that Defendants acted "knowingly" in presenting, making, or using a false claim. *See, e.g.*, 31 U.S.C. §3729(a); *see also Escobar*, 136 S. Ct. at 1996.[12] The complaint suffers from three fatal flaws in connection with the scienter requirement.

First, as discussed above, Relator fails to adhere to Rule 9(b)'s requirement that she identify the who, what, where, when, and how of the alleged fraudulent conduct. Because Relator cannot allege that Defendants *knowingly* presented a false claim without first identifying the false claim allegedly presented, Relator has failed to allege scienter, and her complaint must be dismissed.

Second, Relator fails to account for the inherent subjectivity of the key concepts at the center of the overlapping surgery Billing rule. The closest Relator comes to alleging falsity is to suggest that Defendants incorrectly certified compliance with applicable laws and regulations governing payment of certain claims. *See, e.g.*, Am. Compl. at ¶ 38 (addressing certifications associated with CMS Form 1500). However, Relator fails to allege how a cer-

[12] The False Claims Act defines "knowing" and "knowingly" as having actual knowledge of information or acting in deliberate ignorance or reckless disregard of the truth or falsity of information. 31 U.S.C. §3729(b)(1); *see also Williams*, 2016 U.S. Dist. LEXIS 178032, at *22. The purpose of the scienter requirement is to avoid punishing "honest mistakes or incorrect claims submitted through mere negligence." *See Williams*, 2016 U.S. Dist. LEXIS 178032, at *22 (citing *United States ex rel. Owens v. First Kuwait Gen. Trading & Contracting Co.*, 612 F.3d 724, 728 (4th Cir. 2010)).

tification on Form 1500 demonstrates that MGH had the requisite scienter. That is particularly problematic where, as here, the key concepts of the rule (e.g., "key and critical" portion and "immediately available") are undefined or left to the professional judgment of the teaching physician. For example, even assuming for purposes of this motion that Form 1500 gives rise to an objective falsehood, Relator cannot establish scienter without some allegation that MGH did not believe the teaching physician's subjective judgment that he or she was present for the "key and critical" portions of the case. Similarly, absent a clear definition of "immediately available," it is not plausible to infer that any alleged falsehood linked to that term was made knowingly or in reckless disregard of the truth. *See, e.g.*, *United States ex rel. Donegan v. Anesthesia Assoc. of Kan. City*, 833 F.3d 874, 878-80 (8th Cir. 2016) (affirming summary judgment in favor of defendant based on ambiguity of undefined term "emergence" in CMS billing guidance).

Finally, while Relator alleges that she and another physician raised concerns about overlapping surgeries in 2011 and 2012, there is no indication that those complaints related to billing issues (as opposed to her personal belief that overlapping surgeries were inappropriate) and, therefore, no plausible basis to infer that Defendants were put on notice of any alleged false claims. In addition, there are no allegations at all reflecting upon Defendants' knowledge of alleged falsity prior to 2011. For this reason, as well, Relator's claims should be dismissed.

III. Relator's State Law Claims Fail.

Because the Massachusetts False Claims Act is modeled after the Federal False Claims Act, Massachusetts Courts look to cases and treatises interpreting the Federal Act for guidance in interpreting and applying the state law. *Massachusetts v. Mylan Labs.*, 608

F. Supp. 2d 127, 140 (D. Mass. 2008); *see Scannell v. AG*, 70 Mass. App. Ct. 46, 49 n.4 (2007) ("[t]he MFCA was modeled on the similarly worded Federal False Claims Act, 31 U.S.C. §§ 3729 et seq. … Therefore, we look for guidance to cases and treatises interpreting the Federal False Claims Act."); *see also New York v. Amgen Inc.*, 652 F.3d 103, 109 (1st Cir. 2011) (same). For the reasons her Federal False Claims Act claims fail, Relator's state law claims must also fail. Indeed, the gap between Relator's allegations and what the law requires is even more stark. Plaintiff has made no allegations at all regarding claims paid by the state. Medicaid is not age-based, consequently, even her unsupported assumptions—based on data about older patients having orthopedic surgery, *see supra* at p.8—have no bearing on whether any particular surgery resulted in MGH making a claim for payment to the Medicaid program.

CONCLUSION

For the reasons set forth above, this Court should dismiss this action, with prejudice, pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b).

Respectfully submitted for Defendants,

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August 14, 2017

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as unregistered participants on August 14, 2017.

/s/ Martin F. Murphy
Martin F. Murphy